

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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1. I am a British citizen resident at 16 Heol Neuadd Cogan, Penarth, South Glamorgan CF64 3RQ, United Kingdom.
2. I hold a Bachelors degree in Medicine (BM), a Doctorate of Medicine (DM), and am a Member of the Royal College of Surgeons (MRCS) in the United Kingdom.
3. I currently hold the position of Registrar in Urology at the Royal Gwent Hospital, Newport, Wales, United Kingdom.
4. I have undertaken research in urology, which is my full-time specialty, and have 8-9 years experience in this field.
5. I am an inventor of the invention which is the subject of U.S. patent application 10/596,934 (herein, the "invention").
6. The invention is for treating bladder overactivity, typically causing urge incontinence, and requires the bladder to be distended by liquid to a volume at

which electrical activity in the bladder wall is detected. This activity is indicative of detrusor overactivity, and is mapped. Treatment of the site of activity is by ablation.

7. Liquid, typically saline solution, is infused into the bladder through the urethra from a raised reservoir (e.g., a bag). When the bladder is distended, the reservoir may be lowered so that backfilling ceases. Further lowering allows the bladder to void, or alternatively the reservoir may be disconnected to allow the patient to void naturally.
8. In the invention it is important to hold the bladder at a fixed volume whilst the electrical activity is detected and treated. This ensures accuracy of treatment at the site of electrical activity, which in turn minimises the necessity of a subsequent procedure. Such mapping of the bladder's electrical activity and treatment of the bladder take a considerable period of time to accomplish. Accordingly, the apparatus of the invention includes an external closure for the filling lumen that can be closed to maintain the bladder at the desired fixed volume for the period of time needed for mapping and treatment.
9. I have reviewed U.S. Patent No. 5,662,108 (herein, "Budd"). Budd discloses a mapping device for a heart chamber. The heart is quite different from the bladder, being an organ that beats constantly and rapidly. In contrast a bladder is relatively passive – filling slowly and being voided infrequently.
10. Budd has no means of holding the heart at a fixed volume, and to do so would cause a cardiac arrest. Budd does include a valve on the filling lumen of a balloon catheter, but this balloon does not control the volume of the pumping chamber of the heart (which is equivalent to the bladder in the invention) into which it is inserted.
11. I have also reviewed U.S. Patent No. 6,931,276 (herein, "Streng"). Streng detects electrical activity in a human bladder as it is backfilled. Streng does not disclose mapping of the source of the activity. Although not stated in Streng, I would expect Streng to backfill the bladder using a reservoir raised above the patient on a stand – somewhat similar to that used to infuse saline or blood into a blood vessel.
12. I understand that it has been suggested that the invention is an obvious combination of the teachings of Budd and Streng, but I respectfully disagree.
13. There is no reason for Streng to maintain liquid in the bladder after an electrical (micturition) response is detected. Rather, once this response is detected, a medical practitioner using Streng's apparatus would simply drop the reservoir down to allow bladder voiding. To maintain pressure (i.e., by closing an external closure on the filling lumen) would subject the patient to unnecessary discomfort to no purpose, and may have the effect of causing some unforeseen medical complication, such as a deterioration of bladder performance in patients who are already compromised.

Furthermore, holding bladder pressure for a period using Streng's device will achieve nothing that a transient increase in pressure cannot demonstrate by way of electrical response. It indeed could be considered to be medically unethical.

14. Budd in my opinion would be unlikely to be considered by a person skilled in urology. Cardiac medicine is an entirely different specialty with a well-defined medical cohort distinct from that of urology. The two medical disciplines are entirely separate, both in staff and in hospital department.
15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

  
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Jonathan Mark Featherstone

16/01/2009.  
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Date